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OHLANDT, GREELEY, RUGGIERO & PERLE, LLP
ONE LANDMARK SQUARE, 10TH FLOOR
STAMFORD, CT 06901

| EXAMINER | |
|---|---|
| PRICE, NATHAN R | |

| ART UNIT | PAPER NUMBER |
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| 3763 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/601,212 | GILLESPIE, RICHARD D. | |
| | Examiner | Art Unit | |
| | NATHAN R. PRICE | 3763 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *23 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *13-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 June 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/10/2008, 09/23/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Response to Amendment*

1. This office action is responsive to the amendment filed on June 25, 2007. As directed by the amendment: no claims have been amended, claims 1-12 have been cancelled, and new claims 33-38 have been added. Thus, claims 13-38 are presently pending in this application.

### *Double Patenting*

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory

double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 13-38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6387078. Although the conflicting claims are not identical, they are not patentably distinct from each other because the limitations of the pending claims are claimed in the patent.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 26 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim element "means for releasably securing said syringe assembly in a retracted position" is a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to clearly link or associate the disclosed structure, material, or acts to the claimed function such that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function.

Applicant is required to:

(a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it clearly links or associates the corresponding structure, material, or acts to the claimed function without introducing any new matter (35 U.S.C. 132(a)); or

(c) State on the record where the corresponding structure, material, or acts are set forth in the written description of the specification that perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 13, 14, 18-24, 26-30, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Crossman et al. (US 5300030).

8. Regarding claims 13 and 14, Crossman et al. discloses an injection apparatus comprising: a first chamber 18 (fig. 1) containing a medicine; a plunger 27 (fig. 1) cooperating with said first chamber, said plunger having a first engaging member 8 (fig. 1) defined thereon; a needle 22 (fig. 1) in fluid communication with said first chamber; a coupling (rear end of barrel 1, fig. 1) having a second engaging member 11 (fig. 1) defined in an inner periphery, said first and second engaging members being releasably

engaged to one another (see fig. 1-2); and a first spring 19 (fig. 1) acting on said coupling to urge said plunger in a first direction (via rearward force on syringe elements, see fig. 1-2) until said coupling contacts a surface 4 (fig. 2), wherein said surface causes said second engaging member to move away from said plunger so that said first and second engaging members are released from one another (see fig. 1-2; col. 3, ln. 3-11); said first chamber and said needle are movably disposed in a housing (see fig. 1-2).

9. Regarding claims 18-24, 26-30, and 32, Crossman et al. discloses an injection apparatus comprising: a syringe assembly (syringe comprising element 18 in fig. 1) having a needle 22 (fig. 1), a first chamber (chamber within 18, fig. 1) for holding a medicine, and a plunger 27 (fig. 1) operable to force said medicine from said first chamber through said needle; a first engaging member 29 (fig. 1) being defined on said plunger; a housing 1 (fig. 1) being disposed about said syringe assembly so that said syringe assembly is movable in said housing between a retracted position (fig. 1) and an extended position (fig. 2), said housing concealing said needle in said retracted position (see fig. 1), and said needle extending from said housing in said extended position (see fig. 2); a first spring 14 (fig. 1) for driving said syringe assembly from said retracted position to said extended position (see fig. 1-2) and for causing said plunger to drive said medicine through said needle (see fig. 1-2); a coupling 8 (fig. 1) being disposed between said first spring and said plunger, said coupling having a second engaging member 13 (fig. 1), said coupling having a closed position (fig. 1-2) and an open position (fig. 3-4), said first and second engaging members being engaged to one

another when said coupling is in said closed position so that said plunger is drivably engaged with said first spring (see fig. 1-2), and said first and second engaging members being disengaged from one another when said coupling is in said open position so that said plunger is disengaged from said first spring (see fig. 3-4); and a surface (interior of housing 1 and elements 21 connected thereto, fig. 1) being defined in said housing for moving said coupling from said closed position to said open position after said plunger forces said medicine from said first chamber through said needle (see fig. 3 and 4); said surface slopes radially away from said plunger (surface of 21 slopes back to connet to syringe body 1, see fig. 1 and 2); said first engaging member is a groove circumferentially defined on said plunger (see fig. 1-4) and said second engaging member is a lip circumferentially defined on an inner face of said coupling (see fig. 1-4); said coupling further comprises a plurality of openable portions having said second engaging member thereon (portions of 8 interacting with interior of barrel 1, fig. 1-4); first spring drives said plurality of openable portions over said surface (over interior of barrel 1, fig. 1-4) to open said portions until said first and second engaging members disengage (as shown in fig. 3-4); a second spring 19 (fig. 1) for driving said syringe assembly from said extended position to said retracted position after said coupling is moved to open position; and means for releasably securing said syringe assembly in said retracted position (apparatus within cap 3, fig. 1-4).

10. Regarding claims 32-34, 36, and 37, Crossman et al. discloses an automatic injecting apparatus comprising: a housing 1 (fig. 1) having a cavity and a proximal and a distal end;a syringe assembly (syringe assembly disposed within apparatus of fig. 1

comprising 18) within the housing, the syringe assembly further comprising: a first chamber (chamber within 18, fig. 1) for holding a liquid; a needle 22 (fig. 1); and a plunger 27 (fig. 1), the plunger having a plunger shaft disposed proximally, the plunger being operable to force the liquid from the first chamber; the plunger shaft engaging a spring-to-plunger coupling ("spring-to-plunger coupling" comprising engagement of rear end of plunger 27 and element 8, fig. 1); a driver spring 14 (fig. 1) within the housing, engaging the spring-to-plunger coupling, operable to the syringe assembly to inject the needle and displace the liquid medicine through the needle (see fig. 1-4); and a splitter 21 (fig. 1) attached to the housing distally to the spring-to-plunger coupling; the splitter having a surface for engaging the spring-to-plunger coupling (indirectly by engaging 20, which engages 27) and forcing the spring-to-plunger coupling to disengage from the plunger shaft (see fig. 3 and 4), thereby disengaging the driver spring from the syringe assembly; the plunger shaft further comprises a circumferential groove 29 (fig. 1); and, the spring-to-plunger coupling further comprises: a plurality of axial slits (slits formed in rear end of plunger 27, fig. 1); and a radial lip (interior projection of 13, fig. 1) for releasably engaging the circumferential groove (see fig. 1-4), so that the radial lip disengages from the circumferential groove as the spring-to-plunger coupling engages the splitter (see fig. 3-4); a return spring 19 (fig. 1); at least two compressible barbs 12 (fig. 1); the barbs connected to the proximal end of the plunger shaft (via connection between element 8 and plunger shaft 27, fig. 1); the housing having a housing cap 3 (fig. 1); a rod 4 (fig. 1-2) disposed within the housing cap; the rod having an interior bore (area between 4 and 5, fig. 1-2) sized to receive the barbs in their compressed state

(col. 3, ln. 3-11); and, a detent 11 (fig. 1-2) integral with the housing cap; the detent sized to engage the barbs in their uncompressed state (see fig. 1) and prevent the distal movement of the plunger shaft until the barbs are compressed.

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crossman et al. Crossman et al. discloses the apparatus as claimed, including a second spring 14 (fig. 1) for urging said first chamber and said needle in a second direction (see fig. 1-2); said second spring moves said first chamber and said needle in said second direction once said first and second engaging members are released from one another (as shown in fig. 2), except for said second spring being weaker than said first spring. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the springs of Crossman et al. to a desired weakness in relation to one another in order to achieve a desired speed of insertion/injection and a desired speed of retraction.

13. Claims 17, 25, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crossman et al. in view of STI (WO 9409839). Crossman et al. discloses the apparatus as claimed except for a damper pad disposed between said housing and said first chamber so that an impact of said first chamber with said housing

is dampened. However, STI teaches a pad 40 (fig. 1) disposed between the housing and the first chamber (se fig. 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Crossman et al. apparatus such that it comprises a damper pad disposed between said housing and said first chamber so that an impact of said first chamber with said housing is dampened, for the purpose of preventing damage to the housing or the chamber upon use of the device.

14. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crossman et al. in view of Brown (US 2717601). Crossman et al. discloses the apparatus as claimed except for a second chamber for holding a liquid; a disk disposed between the first chamber and the second chamber; the disk releasably sealing the first chamber from the second chamber; and, at least one aperture in the wall of the second chamber allowing liquid communication between the portion of the second chamber proximal to the disengaged disk and the portion of the second chamber distal to the disengaged disk, so that the liquid flows through the second chamber before being forced through the needle. However, Brown teaches a syringe design comprising a first and second chamber (15 and 16, fig. 1), a disk 14 (fig. 1) releasably sealing the chambers, and an aperture 13 (fig. 1) in the wall allowing liquid communication (see fig. 2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Crossman et al. apparatus such that it comprises a second chamber for holding a liquid; a disk disposed between the first chamber and the second chamber; the disk releasably sealing the first chamber from the second chamber; and at least one aperture in the wall of the second chamber allowing liquid

communication between the portion of the second chamber proximal to the disengaged disk and the portion of the second chamber distal to the disengaged disk, so that the liquid flows through the second chamber before being forced through the needle, as taught by Brown, for the purpose of maintaining a diluent and a medicament in a sterile condition until injection (col. 1, ln. 21-25).

15. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crossman et al. in view of STI. Crossman et al. discloses the apparatus as claimed except for a flexible septum; the flexible septum disposed proximally to the proximal end of the needle and sealing the needle from the second chamber; so that liquid pressure in the chamber causes the septum to deflect distally until the septum is penetrated by the proximal end of the needle. However, STI discloses such a flexible septum 32 (fig. 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Crossman et al. apparatus such that it comprises a flexible septum; the flexible septum disposed proximally to the proximal end of the needle and sealing the needle from the second chamber; so that liquid pressure in the chamber causes the septum to deflect distally until the septum is penetrated by the proximal end of the needle, as taught by STI, for the purpose of preventing medicament injection until the needle is advanced (see fig. 5 and 6).

***Response to Arguments***

16. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Gillbert (US 7097634).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATHAN R. PRICE whose telephone number is (571)270-5421. The examiner can normally be reached on Monday-Thursday, 9:00 a.m. - 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. R. P./
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763